



Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) Publication number:

0 387 630
A2

(12)

EUROPEAN PATENT APPLICATION

(21) Application number: 90104075.8

(51) Int. Cl. 5: G01N 21/78

(22) Date of filing: 02.03.90

(30) Priority: 13.03.89 US 324403

(43) Date of publication of application:
19.09.90 Bulletin 90/38

(84) Designated Contracting States:
DE FR GB IT

(71) Applicant: MILES INC.
1127 Myrtle Street
Elkhart, IN 46515(US)

(72) Inventor: Hurtle, Richard L.
23549 U.S. 33 East
Elkhart, Indiana 46515(US)
Inventor: Vavul, Thomas E.
10193 Parkwood Drive, Apt. Nr. 1
Cupertino, California 95014(US)

(74) Representative: Kirchner, Dietrich, Dr. et al
c/o BAYER AG Konzernverwaltung RP
Patentabteilung
D-5090 Leverkusen, Bayerwerk(DE)

(54) A compact semi-programmable device for reading reagent test strips and method relating thereto.

(57) A portable photoanalytical device takes a reflectance reading from a reagent test strip, compares the reading to an internal standard, and translates the reading to a concentration value using constant values stored within a RAM chip. The constant values are preprogrammed for a particular lot of reagent test strips. A battery maintains the information stored in the RAM. The control values are initially downloaded into the RAM via an external connector. The concentration values are accumulated in the RAM, and periodically dumped out of the device through the external connector. The integrity of the information stored in the RAM is monitored by computing a checksum. Preferably the device includes a battery-backed real-time clock providing the date and hour of each reading. The device can also be operated by an external computer for test purposes.

EP 0 387 630 A2

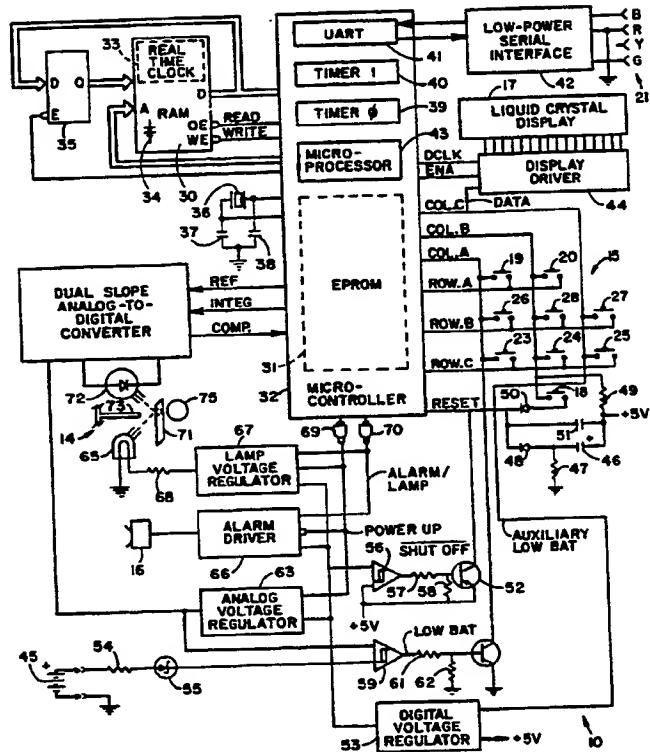


FIG. 4

A COMPACT SEMI-PROGRAMMABLE DEVICE FOR READING REAGENT TEST STRIPS AND METHOD
RELATING THERETO

BACKGROUND OF THE INVENTION

5 A. Field Of The Invention

The present invention relates generally to a compact photoanalytical device for use in reading reagent test strips. More specifically, the photoanalytical device of this invention can be used by medical technicians or diabetics for automatically reading test strips that indicate blood glucose concentration by a 10 change in color.

15 B. Description Of The Related Art

Patients suffering from diabetes mellitus require periodic doses of insulin to maintain their blood 20 glucose concentration within safe limits. The required dosage for any given patient is influenced by a number of environmental variables such as stress, exercise and dietary intake. Therefore, it is necessary for the blood glucose concentrations of patients to be closely monitored to periodically adjust the dosage of insulin.

In many cases the patient's blood glucose concentration must be measured multiple times a day. For 25 this purpose, techniques and instruments have been devised that enable the patient to make the measurements at home. In the typical case the patient records the measurements for periodic review by the physician during scheduled office visits, and the patient may seek the immediate aid of the physician if the measurements are abnormal. In some cases the patient is instructed to adjust the insulin dosage based on the measurements.

An especially simple and reliable diagnostic or test procedure is required if the procedure is to be performed by the patient at home, without the assistance of a physician or experienced technician. Such 30 procedures may use reagent test strips that change color in the presence of a specific chemical substance such as blood glucose. In addition the intensity of the color change must be a predetermined function of the concentration of the chemical substance in order to provide a quantitative measurement. The concentration of the chemical substance can then be estimated by comparing the color of the test strip to a color chart that has been calibrated in terms of concentration.

In a conventional procedure for blood glucose measurement, the patient pricks his or her finger with a lancet and obtains a drop of blood. The blood is placed on a reagent test strip sensitive to blood glucose. 35 After forty seconds, the strip is wiped with an absorbent tissue to remove excess blood. Twenty seconds later the color of the strip is compared to the calibrated color chart.

The use of a color chart requires the patient to make an evaluation or estimate. To enable the physician to monitor the patient's condition, the patient must record his or her estimate of the blood glucose concentration, along with the date and time that the measurement was taken. The patient's estimation, 40 however, is subject to errors of judgment, and the recording of data is also subject to errors. To eliminate these errors a hand-held instrument has been devised for sensing the reflectance of a test strip at the proper time, converting the reflectance to blood glucose concentration, and recording the blood glucose concentration.

A hand-held instrument for measuring and recording blood glucose concentrations from reagent test 45 strips is disclosed in Allen, III, U.S. Patent 4,731,726 issued March 15, 1988. The instrument includes a reflectance photometer having a light emitting diode and a phototransistor, and a microcomputer for performing the measurement by operating the reflectance photometer, converting reflectance to glucose concentration, and recording the glucose concentration and other data. The microcomputer includes a keyboard for receiving data from the patient and a display for displaying commands and blood glucose 50 concentrations. The microcomputer also has a timer and an audio output unit to provide "beep" signals to the patient. The patient, for example, activates a key on the keyboard to signal the start of a sixty-second test interval, and the timer and audio output unit provide a "beep" signal after forty seconds so that the patient wipes the test strip at that time and then places the test strip in the optical reflectometer. At the end of the sixty-second test interval, the microcomputer obtains a reflectance reading from the reflectometer by

operating an analog-to-digital converter.

Allen says that his monitor system can be used with a communications modem to communicate with a physician's base station over a telephone line. (Col. 6, lines 28 et seq.) The physician's computer implements an algorithm for evaluating glucose and patient data from the monitor system, and the patient's insulin prescription may be adjusted in response to the evaluation and transmitted to the monitor via the modem link. The monitor, operating independently of the modem link is said to allow a patient to use and evaluate glucose, insulin and behavioral data on a daily basis. Accumulated patient data is communicated to the physician's computer through the modem link and the computer evaluates the data to produce a patient report. The physician interprets the report results and depending on his or her analysis, may revise assessment parameters, dietary and/or insulin prescriptions. The physician may then reprogram the monitor system by changing the assessment parameters or dietary, insulin, or other prescription stored within the monitor. It is said that this can be done by data inputs applied to the monitor directly at the physician base station or remotely over the modem channel.

Allen says that his glucose reflectance photometer can distinguish a large number of color shades. (Col. 8, lines 23 et seq.). Each shade of blue or other color corresponds to a certain blood sugar level. The monitor can be programmed so that other types of reagent strips can be used. Allen says that in such a case an adjustment in the A/D converter control software would also be required to provide correct conversion values.

A hand-held blood glucose meter including a microcomputer and an optical reflectometer for reading reagent test strips has been manufactured and sold by Miles, Inc., Diagnostics Division, Elkhart, Indiana 46515. The Miles blood glucose meter has an internal clock and calendar that automatically keep track of testing times. The stored results include date, time and glucose values. Visual warnings are provided for low battery, high and low glucose readings, and internal errors. A capacitor ensures that the memory retains data for at least eight hours even when the battery is removed for replacement.

25

SUMMARY OF THE INVENTION

The present invention specifically pertains to a control means and method for adapting a portable photoanalytical device to particular reagent test strips, operators and users, and documenting the calibration and performance of the device. Briefly, in accordance with the invention, the photoanalytical device includes a random access memory (RAM) chip that stores at least one constant that is downloaded through an external connector. A battery maintains the information within the RAM chip. The constant value is used by the device in a software program for translating reflectance readings into concentration values. A switching means is provided for initiating execution of the software program for taking a reflectance reading from a reagent test strip within the device and comparing the reflectance reading to an internal standard. The reading is translated to a concentration value using said constant value and said concentration value is stored within the RAM chip. The stored concentration value is then capable of being outputted through the external connector. The feasibility of such a device is ensured by further providing an internal data integrity (IDI) means for determining whether the information maintained within the RAM chip is erroneous and displaying an appropriate message in the event that the information is erroneous.

Preferably the reflectance readings are translated into concentration values using both downloaded constants, which are predetermined in accordance with the type of reagent test strips to be used, and an activity level that is determined for each lot of reagent test strips. Each bottle of test strips, for example, is marked with the activity level. The portable photoanalytical device is provided with a keyboard to enable the operator to enter or change the activity level.

To minimize erroneous entry of the activity level, the operator is required to enter it only once and that activity level is stored in the RAM. During subsequent times that the device is turned on, the previously stored activity level is displayed and the operator may change it when necessary to match the activity level of a new bottle of test strips. Only a small number of possible activity levels is needed due to the use of appropriately selected downloaded constant values for translation of reflectance to concentration. The IDI means therefore ensures both the validity of the downloaded constant values and the previously entered activity level, and in particular can be used to prevent a reading from being taken in the event of erroneous RAM information unless the constant values are corrected by subsequent downloading and a new activity level is entered by the operator via the keyboard.

In accordance with another feature of the invention, the photoanalytical device includes a battery-backed real time clock and a microprocessor. The microprocessor is programmed to read the real time

clock and provide an alarm clock function for ensuring that the required steps are performed at the required times for each reading. The microprocessor can also be programmed to keep track of a calibration or treatment schedule and to indicate that an appropriate reading was not taken at an appropriate time.

In accordance with still another feature of the invention, the microprocessor is programmed to provide a setup and manufacturing test mode in which constants and control limits can be set and verified by an external computer, and in which the external computer can operate and test the device and read internal values such as battery voltage and dark and reference levels.

10

BRIEF DESCRIPTION OF THE DRAWINGS

Other features and advantages of the invention will become apparent upon reading the following detailed description and upon reference to the drawings in which:

15 FIG. 1 is a pictorial view of a hand-held photoanalytical device incorporating the present invention and illustrates its display, keyboard and test chamber;

FIG. 2 is a plan view of the display showing all display elements and legends;

FIG. 3 is a detailed view of the keyboard and illustrates the legends for the various keys;

20 FIG. 4 is a system-level schematic diagram illustrating the electronic components of the photoanalytical device of FIG. 1;

FIG. 5 is a detailed schematic diagram of the electronic components which assure the integrity of information stored in a random access memory;

FIG. 6 is a graph illustrating the operation of a dual slope analog-to-digital converter used in the photoanalytical device of FIG. 1;

25 FIG. 7 is a detailed schematic diagram of the electrical components in the dual slope analog-to-digital converter;

FIG. 8 is a detailed schematic diagram of a low power serial interface used for downloading information through an external connector into random access memory;

30 FIG. 9 is a hierarchical diagram of top-level software modules which are executed by a microcontroller in the photoanalytical device of FIG. 1 during downloading of control information, during testing and operation of the device, and during the retrieval of concentration values and other data accumulated in the random access memory;

FIG. 10 is a hierarchical diagram of the software modules for various operating sequences;

FIGS. 11A and 11b show a flowchart which illustrates the operation of the photoanalytical device of

35 FIG. 1;

FIG. 12 illustrates flowchart steps which could be used for activating an alarm to remind an operator to take a reading according to a prestored calibration or treatment schedule;

FIG. 13 shows flowchart steps that could be used for determining the next time that a reading should be taken according to the prestored schedule; and

40 FIG. 14 shows flowchart steps that could be used to indicate that appropriate readings have not been taken at appropriate times in accordance with the prestored schedule.

While the invention is susceptible to various modifications and alternative forms, a specific embodiment thereof has been shown by way of example in the drawings and will herein be described in detail. It should be understood, however, that it is not intended to limit the invention to the particular form disclosed, but on the contrary, the intention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the invention as defined by the appended claims.

50

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Turning now to the drawings, there is shown in FIG. 1 a hand-held photoanalytical device generally designated 10 which incorporates the present invention. The instrument 10 takes optical readings of reagent test strips of the kind which indicate the concentration of a substance such as blood glucose by a change in the reflectance of the strip.

55 To read the reflectance of a test strip (71 in FIG. 4), the instrument 10 has a test chamber generally designated 11 underneath a cover 12. After raising the cover, the test strip is inserted into a guide 13 that aligns an end portion of the strip with an optical reflectometer generally designated 14. The reflectometer

takes a reflectance reading of the strip and the reading is compared to an internal standard obtained by measuring a "dark level" and a "reference level" as will be further described below. By this comparison process the reflectance reading is normalized to a reflectance of between 0 and 100 percent.

In order to convert the normalized reflectance to concentration, it is necessary to employ a calibration procedure that takes into account the specific characteristics of the reagent test strip. In particular the normalized reflectance of a test strip is not a linear function of concentration. Moreover, the sensitivity of a test strip to concentration is a function of the particular lot or bottle from which the test strip is obtained. Therefore, it is necessary to employ preprogrammed constants for translating the normalized reflectance to concentration, and it is also necessary to employ an "activity" value for the particular lot or bottle from which the test strip is obtained. Bottles of test strips, for example, are commercially available from a number of manufacturers and each bottle is labeled with an activity value.

In order to initiate the taking of a reflectance reading from a test strip, the instrument 10 includes a keyboard generally designated 15. The instrument 10 further includes a buzzer 16 and a display generally designated 17 for guiding the operator through a test procedure and displaying the concentration value that is obtained for the test strip. In particular, the keyboard 15 includes an on/off button 18 for turning the device 10 on and off. The keyboard also includes a "program" button 19 for selecting the activity level associated with the particular test strip. To initiate the taking of a reflectance reading, the keyboard also has a "start" button 20.

In accordance with an important aspect of the present invention, the instrument 10 has an external connector 21 for downloading and uploading control information from an external computer (not shown) to a random access memory (30 in FIG. 4) inside the instrument 10. As further described below in connection with FIG. 5, the random access memory is backed-up with a battery thereby allowing perpetual memory storage within the random access memory for the duration of the life of the battery. Preferably a lithium or similar-type battery is used that will last at least ten years before it need be replaced. In addition, the instrument 10 includes an internal data integrity (IDI) means for determining whether the information maintained within the random access memory is erroneous and for displaying an appropriate message on the display 17 in the event that the information is erroneous. Preferably this is done by computing a check sum of all the information in the random access memory whenever that information is changed. The check sum itself is stored in the memory. At a later time the check sum is recomputed and the result tested to determine the internal data integrity. Therefore, by backing the random access memory with a long-life battery, and providing the internal data integrity means, the random access memory can be used to store control information that previously had been stored only in a nonvolatile memory such as a mask programmable or electrically programmable read only memory.

In accordance with another aspect of the present invention, the instrument 10 includes a real-time clock (33 in FIG. 4) that preferably is backed by the same long-life battery as the random access memory. The real-time clock then can be used for automatically recording the date and time when the device is used to take reflectance readings or is calibrated or reprogrammed.

In accordance with still another aspect of the present invention, the instrument 10 is programmed with procedures and operating sequences for initial programming and testing, and for taking reflectance readings and accumulating results in the random access memory. The accumulated results are periodically uploaded or dumped via the external connector 21 to an external computer or printer (not shown).

When the instrument 10 is used in accordance with the operating procedures, the operator interacts with the device via the keyboard 15 and the display 17. The device 10 can be programmed for operation by a medical technician to perform tests for a number of patients, or the device 10 can be programmed for the exclusive use of a single patient. In the former case, the device 10 is programmed to accumulate calibration data in the random access memory in order to provide a permanent record validating the measurements obtained with the device. In the latter case, the device 10 is programmed to accumulate the concentration values obtained for a particular patient in order to provide a permanent record of patient data for review by a physician to aid in diagnosis or treatment.

At present, it is believed that initially the present invention will be most advantageous for monitoring different operators regarding their ability to properly operate the instrument 10 and to provide a record of calibration data validating the measurements made with the instrument. In this case, the instrument is programmed to run control sequences and to accumulate the results of the control sequences in the random access memory.

To run a control sequence, the instrument 10 is first turned on by pressing the on/off switch 18. A program number appears on the display 17 and remains displayed until another button is pressed. The program number represents the procedure by which normalized reflectance of a test strip is converted to a concentration value. In other words, it represents an "activity level" for the strip. Therefore the instrument

can read a number of different kinds of reagent strips.

The operator can chose the program number or "activity level" for the particular strip to be used by pressing the program button 19. A previously used program number, for example, is fetched from the random access memory and displayed. Each time the operator presses the program button, the program number will index to the next higher number. Once the displayed program number matches the program number identified with the reagent strip, the operator could perform a measurement as described above by pressing the start button 20. But to perform a control sequence, instead, the operator raises a protective cover 22 that normally overlays a series of buttons on the keyboard 15 that are not needed for obtaining patient data.

To initiate the control sequence, the operator presses a "control" button 23. At first the entire display lights up as shown in FIG. 2 thereby providing a test to determine whether the entire display is working properly. Thereafter, the control button can be released.

If the random access memory is full, an error message will then be displayed and the instrument will not take any further readings until data is transferred out of memory. Assuming the memory is not full, the display will show an operator identification number and identify it as such by displaying the "operator" legend. If the operator wishes to change this identification number, the operator can press a "change" button 24 and then a "forward" button 25 or a "reverse" button 26. If the forward button is pressed, the identification number is indexed up, and if the reverse button is pressed, the identification number is indexed down. Once the appropriate identification number is selected, the control button 23 is pressed.

The operator is then required to go through a test run. A standardized control fluid (not shown) must be placed on a reagent test strip (not shown) correlating to the program number or "activity level" previously selected. Once the control fluid is supplied the start button 20 is pressed, the buzzer 16 sounds, "60 seconds" is displayed, and a second-by-second countdown begins.

The buzzer sounds a higher, shorter note at 22 and 21 seconds and a longer, lower note at 20 seconds, whereupon the operator wipes the test strip and inserts it into the guide 13 of the test chamber 11. When the countdown reaches one second, the buzzer 21 sounds a series of five very short buzzes to indicate that if the test strip was not inserted and the door closed, it is too late and the test must be run again. At 0 seconds the reflectance of the test strip is read by the optical reflectometer 14.

If the result is within a specified range, the result is stored in the random access memory along with the date, time, and operator identification number. If the result is outside the specified range, a flashing error message is displayed. The operator must then start all over again until an acceptable result is obtained. The range of acceptable results is defined by upper and lower control limits that are programmed in the random access memory.

Each control reading is stored in the random access memory, and in this way, different operators can be monitored regarding their ability to properly operate the instrument. Furthermore, if the operator cannot operate the instrument, that person cannot proceed and take a test reading. Also, if the instrument is faulty, proper test reading is not possible and therefore the instrument cannot be used to take readings unless it is properly repaired.

In order to set the real time clock, the keyboard 15 has a "clock" button 27. By pressing the clock button, the year, month, day, hour and minute are indexed in sequence and each of these can be increased or decreased by pressing the forward or reverse buttons.

To review results that are accumulated in the random access memory, the keyboard 15 includes a "recall" button 28. By pressing the recall button, the system number, the number of empty data spaces left in the random access memory and the stored results are recalled in sequence.

Turning now to FIG. 4, there is a system level schematic of the electronic components in the instrument 10. The control sequences for the instrument are defined by control information in the random access memory 30 and in an electrically programmable read only memory 31. This control information includes instructions which are executed by a microcontroller 32. Preferably the microcontroller is a type 8051 microcontroller such as part number 85C154 manufactured by OKI. The electrically programmable read only memory 31 preferably is a part number 27C128 that is mounted in piggy back fashion over the microcontroller chip.

The random access memory preferably is a part number DS1243Y manufactured by Dallas Semiconductor, 4350 Beltwood Parkway South, Dallas, Texas 75244. This random access memory includes an 8K byte memory chip in a hybrid package that also includes a real time clock 33 and a lithium battery 34. The real time clock is accessed over the same address and data lines as the random access memory chip.

The type 8051 microcontroller 32 multiplexes the lower order 8 address bits over the data lines and therefore an address latch 35 such as part number 74HC373 is used in connection with the random access memory 30.

The microcontroller 32 executes instructions at a precise rate set by a quartz crystal 36 preferably having a frequency of 1.8432 megahertz. The crystal 36 operates in connection with two 15 picofarad capacitors 37 and 38. The frequency provided by the crystal clocks two timers in the microcontroller. The first timer, designated as "timer 0", provides a one-millisecond interrupt which is counted by an interrupt routine to provide a first number indicating milliseconds and a second number indicating seconds. These numbers are used for controlling timing for scanning the keyboard 15, flashing or displaying data on the display 17, sounding the buzzer 16, and for controlling the 60 second countdown for taking a reflectance reading.

The frequency of the quartz crystal 36 clocks a second timer 40 referred to as "timer 1" that sets the baud rate of a universal receiver-transmitter or UART 41. The UART is linked to the external connector 21 by a low-power serial interface 42. This serial interface preferably receives and transmits data through the connector 21 according to the standard RS232 protocol.

At the center of the microcontroller is a microprocessor 43 which executes instructions fetched from memory and has internal registers for the temporary storage of data and intermediate results.

For low power operation, the display 17 is preferably a liquid crystal display. As shown in FIG. 4, the display 17 is interfaced to the microcontroller via a display driver such as a Motorola MC145000 which has a serial input shift register.

For protecting the integrity of the data stored in the random access memory 30, the microcontroller 32 must be prevented from writing data to the RAM 30 when power is first supplied to the circuits or when power is removed. Power to the microcontroller is supplied, for example, by a 9 volt battery 45 including six size "AA" cells. When these cells are inserted or removed from the instrument, it is necessary to prevent the microcontroller from writing data to the random access memory 30. This is conveniently done by providing circuits which hold the microcontroller in its reset state during these conditions.

When the battery cells are first inserted, the microcontroller is reset by a circuit including an electrolytic capacitor 46, a resistor 47, and a directional diode 48. The capacitor, for example, has a value of 10 microfarads, and the resistor has a value of 8.2K ohms. It is also possible, though unlikely, that the microcontroller would need to be reset during some other time. To account for this possibility, the on/off push button switch 18 functions as a reset switch in connection with a resistor 49, a directional diode 50 and a capacitor 51. The resistor 49, for example, has a value of 4.3 K ohms, and the capacitor has a value of 0.1 microfarads.

To ensure the integrity of the data in the random access memory 30, it is also necessary to hold the microcontroller in its reset state whenever the voltage from the battery 45 drops to a level insufficient to power the microcontroller 32 with at least 5 volts. For this purpose the power supply circuits activate a transistor 52 to supply a reset signal in this case. Therefore, the instrument stops functioning and consequently the operator is forced to replace the battery 45.

The power supply circuits include a voltage regulator 53 such as part number MAX666 which provides 5 volts to the microcontroller and its associated digital circuits. The power supply circuits also include a current limiting resistor 54, for example 1 ohm, and a Schottky diode 55 to ensure against improper battery polarity.

To provide the shut off signal in the event of a low battery voltage, a Schmitt trigger comparator 56 compares the battery voltage to a relatively constant reference voltage such as the output of the voltage regulator 53 to provide a shut off signal active low when the battery voltage drops below about 5.5 volts. In this case, the comparator 56 turns the transistor 52 on through a current limiting resistor 57 and a shunt resistor 58, for example, both 100 K ohms.

In order to prevent the microcontroller from being shut off during use due to a low battery, the display 17 (see FIG. 2) has a "low bat." indicator to give the operator advanced warning of a low battery. This condition is detected by a second Schmitt comparator 59, a transistor 60, and resistors 61 and 62, for example, both 100 K ohms. The comparator 59 compares the battery voltage to the relatively constant output of an analog voltage regulator 63. The Schmitt trigger 59, for example, provides a low battery signal whenever the battery voltage drops to about 6.3 volts. An auxiliary low battery signal is provided by the part number MAX666 voltage regulator 53. And as an added precaution the microcontroller 32 can sense the auxiliary low battery signal as well as the low battery signal from the comparator 59.

The circuits shown in FIG. 4 draw a maximum amount of current when the buzzer or alarm 16 is activated and when a lamp 65 is turned on to take a reflectance reading. The buzzer 16 can operate over a wide voltage range and therefore the battery voltage 45 is selectively applied to the buzzer 16 by an alarm driver 66 that functions as a controlled switch. The alarm driver 66, however, has gating inputs that prevent the buzzer from being turned on at the same time as the optical reflectometer 14.

Although the lamp 65 can also operate over a wide voltage range, it is necessary for the lamp to

provide a relatively constant optical output and therefore its current is maintained relatively constant by a lamp voltage regulator 67 and a current limiting resistor 68, for example, 24 ohms. To ensure that both the buzzer and the lamp are shut off when the microcontroller is reset, the lamp voltage regulator and the alarm driver 66 are connected to the microcontroller through a pair of inverters 69 and 70.

5 To sense the reflectance of the test strip 71, reflected light from the lamp 65 is received by a photodiode 72. A barrier 73 prevents direct transmission of light from the lamp to the photodiode. A dual slope analog-to-digital converter 74 converts photocurrent from the diode to a digital signal providing the microcontroller with a numerical value of the light reflected by the strip 71. To normalize the measured reflectance, it is necessary to compare the reflectance of the strip 71 to the reflectance of a standard such
10 as a mirror 75. The mirror 75 is mounted on the lower surface of the cover 12 of the test chamber (see FIG. 1) so that light is reflected from the lamp 65 to the photodiode 72 when the strip is absent from the test chamber and the cover is closed.

Turning now to FIG. 5 there is shown a detailed schematic diagram of the electronic circuits which enable and power the random access memory 30. These circuits prevent data from being written into the
15 random access memory when the microcontroller is being reset and also selectively couple the power supply of the instrument to the battery 34 in the random access memory 30 in order to extend the life of the internal battery.

The random access memory 30 has a chip enable (CE) input which must be active in order the enable data to be written into the memory. A pair of gates 80, 81 disable the random access memory when the
20 output P1.2 of the microcontroller 32 is high. This occurs when the microcontroller 32 is in its reset state. To disable the memory 30 when the microcontroller 32 is being reset, a transistor 83 senses the level of the reset signal applied to the microcontroller. The transistor 83 operates in connection with a series resistor 84 such as 3.3 megohms and a pull-up resistor 85 such as 1 megohm.

The internal battery 34 is connected to a VCC input of the random access memory 30. If the external
25 supply voltage of +5 volts (from the regulator 53 in FIG. 4) is applied to the input VCC, however, the random access memory will draw current from the external supply rather than the internal battery 34. But it is desirable to connect the internal battery 34 to the external supply in such a way that the internal battery will not be discharged when the external supply loses its voltage due, for example, to the main battery (45 in FIG. 4) having a low voltage. For this purpose, the external supply of +5 volts is connected through a
30 transistor 86 to the input VCC of the random access memory 30. It is also desirable to wire the power supply VCC of the latch 35 in parallel with the input VCC of the random access memory 30 to ensure the stability of the address inputs to the random access memory. Standard supply decoupling capacitors 87 and 88, such as 0.1 microfarads, are also connected to each of the power supply inputs VCC.

For testing the internal battery 34, the microcontroller 32 can disconnect the external supply from the
35 random access memory 30. For this purpose an output P1.1 of microcontroller 32 turns the transistor 86 on and off. Since the output P1.1 is set high when the microcontroller 32 is reset, it is desirable to connect the output P1.1 to the transistor 86 through another transistor 89 and resistors 90, 91 and 92. The resistors 90 to 92 have, for example, values of 1 megohms, 33 K ohms and 120 K ohms, respectively.

Turning now to FIG. 6 there is shown a graph illustrating the operation of the dual slope analog-to-digital converter. As is well known, such a converter functions by integrating a current I_s from a zero reference level for a fixed time T_1 and then integrating the difference between the current I_s and a reference current I_{ref} . Preferably the reference current I_{ref} is selected to be about twice the maximum expected current I_p . Therefore, after a certain time T which is usually less than half the preselected time T_1 , the integrated value will fall below the zero reference value. The time T required for the integrated value to fall below the zero
45 reference value is an indication or measure of the value I_p . In particular, the ratio of I_p to the reference current I_{ref} can be calculated according to:

$$50 \quad I_s = \frac{I_p}{I_{ref}} = \frac{T}{T + T_1} \quad (\text{Equation 1})$$

Turning now to FIG. 7, there is shown a detailed schematic diagram of a dual slope analog-to-digital converter 74 that can be operated by the microcontroller 32 to perform the conversion procedure of FIG. 6.
55 The current I_p from the photodiode 72 is integrated by an integrator comprising a capacitor 100 and an operational amplifier 101. The capacitor 100, for example, has a value of 0.022 microfarads, and the operational amplifier 101 is a part number CA3160L. The inputs to the operational amplifier 101 are biased by a voltage divider network including resistors 102, 103, 104 and 105 which have values, for example, of

13 K ohms, 2.5 K ohms, 160 ohms and 1 K ohms.

The photodiode 72 is biased by a resistor 106, for example 200 megohms, to obtain a linear response and to measure the so-called "dark current" from the photodiode 72 in the absence of light being received by the photodiode. Therefore, the response of the photodiode 72 can be integrated in FIG. 6 for illumination ranging from zero to the maximum value provided by the lamp (65 in FIG. 4) and the measured value of the "dark current" can be subtracted from the result to provide an accurate indication of the level of illumination received by the photodiode.

To integrate the current from the photodiode for the preselected time T_1 , the voltage V_c on the capacitor 100 must initially be less than the zero reference level of FIG. 6. For this purpose the converter 74 includes an analog switching means 107 such as an insulated gate field-effect transistor or transmission gate. A suitable field-effect transistor is part number M116.

The switching means 106 is controlled by an INTEGRATE signal from the microcontroller. After initially discharging capacitor 100, the microcontroller opens the switch 107 for integrating the current from the photodiode 72 for the preselected time T_1 . The microcontroller 32 keeps the switching means 107 open for the time T_1 after the voltage V_c exceeds the zero reference level.

A comparator 108, such as part number 2903, senses whether the voltage V_c exceeds the zero reference level. The comparator works in connection with a pull-up resistor 109 such as 100 K ohms, and an input resistor 110 and a feedback resistor 111 that provide some hysteresis. The resistors 110 and 111, for example, have values of 1 K ohms and 1 megohm. The output of the comparator 108 is fed back to the microcontroller so that the microcontroller may start measuring the preselected time T_1 when the comparator output signal (COMP.) assumes a low value.

During the preselected time T_1 the microcontroller 32 repeatedly executes a program loop 102,400 times to determine the expiration of the time T_1 . Then the microcontroller sends a REF. signal to the converter 74 to begin integrating the difference between the current I_p from the photodiode 72 and the reference current I_{ref} . The reference current is obtained from a resistor 112 such as 10 megohms when analog switching means 113 is closed in response to the REF. signal. The analog switching means 113, for example, is an insulated gate field-effect transistor such as part number M116.

The microcontroller 32 then measures the time T by incrementing a counter during each cycle of the above-mentioned loop until the comparator signal (COMP.) assumes a high logical value. At that time the value of T is indicated by the value of the counter.

To normalize the reflectance of the test strip (71 in FIG. 4), the reflectance of the strip, as indicated by the ratio of I_p to I_{ref} , is compared to an internal standard defined by the so-called "dark current" of the photodiode 72 and a "full scale" current obtained when light from the lamp 65 is reflected from the mirror 75 to the photodiode in the absence of the strip 71 (see FIG. 4). Preferably this comparison or normalization is done according to the following equation:

$$R = R_{fs} \frac{I_s - I_{os}}{I_{fs} - I_{os}} \quad (\text{Equation 2})$$

40

I_s is the current ratio defined by Equation 1 above for the reflectance of the strip 71. The value I_{fs} is the ratio of Equation 1 obtained when the mirror 75 is used in lieu of the strip 71 and indicates the reflectance of the mirror. The value I_{os} is the ratio from Equation 1 obtained when the lamp 65 is turned off. In other words, the value I_{os} is the ratio of the so-called "dark current" of the photodiode 72 to the reference current I_{ref} . The constant R_{fs} is the normalized reflectance of the mirror 75 and has a value, for example, of about 90%.

Preferably the values of I_{os} and I_s are measured each time that a 60 second count down occurs and a reflectance reading is taken for the test strip 71. The dark and full scale currents are measured and the ratios I_{os} and I_s are calculated, for example, just prior to the time that the operator is signaled to insert the test strip 71 into the test chamber (11 in FIG. 1).

The consistency of the values used in the normalization procedure are checked by applying predetermined control limits to the measured time T during the analog-to-digital conversion process. When measuring the dark current, the time T_1 must fall within a range of 0 to 9,278 counts. When measuring the full scale current indicating the reflectance of the mirror 75, the time T_1 must fall within a range of about 29,142 to 230,400 counts. When reading the reflectance of the test strip, the time T_1 must fall within a range from the count obtained when measuring the dark current and 230,400 counts.

Once the reflectance of the test strip 71 has been normalized, it is necessary to convert or translate the

normalized reflectance to a concentration value using constant values stored in a random access memory and using a program number or activity level for the particular test strip. It is desirable to perform such a translation using a piece-wise linear or polynomial equation so as to minimize the required number of stored constants and to use conventional algebraic subroutines for performing the computations. Also, it is 5 desirable for the conversion or translation to be done in such a fashion that a small number of activity levels can be used to characterize the test strips.

For measuring blood glucose concentration, the following conversion formula is preferred for enabling the test strips to be characterized by 8 activity levels, designated by a program number P ranging from 1 to 8:

10

$$\begin{aligned}
 F &= A + B \cdot R + C \cdot R^2 \\
 E &= E_0 + (P - 1) \cdot E_1 \\
 D &= D_0 + E \cdot D_1 \\
 15 \quad \text{IF } R > E \\
 &\quad \text{THEN } G = G_0 + F \cdot G_1 \\
 &\quad \text{ELSE } G = G_0 + (F + D \cdot (E - R)^2) \cdot G_1
 \end{aligned} \tag{Equation 3}$$

20 G is the blood glucose concentration, and A, B, C, D0, D1, E0, E1, G0 and G1 are predetermined constants selected to "fit" the above equation to empirical data obtained by measuring the reflectance of a statistically representative sample or group of strips with standardized control solutions.

25 Equation 3 above should be recognized as a kind of "single point" calibration procedure that recognizes that for relatively high values of normalized reflectance, the concentration G is a quadratic function of the normalized reflectance R. But when the concentration G is less than the value E, however, the concentration G deviates from the quadratic function in a "square law" fashion by an amount proportional to the constant D.

30 Once the concentration is computed, it is compared to certain control limits before being displayed to the operator. For blood glucose concentration, for example, any concentration value greater than 2,000 mg/dL is considered erroneous and values at or above this limit are indicated by displaying "error". The instrument 10 also has a range over which the concentrations values are considered sufficiently accurate to be displayed and recorded. The upper limit for accurate glucose concentration values is, for example, 501 mg/dL, and the lower limit, for example, is 20 mg/dL. Readings at or above the upper limit are indicated by displaying "HI" and are recorded as 501 mg/dL. Readings below the lower limit are indicated by displaying "LO" and are recorded as 29 mg/dL.

35 Turning now to FIG. 8 there is shown a detailed schematic diagram of the low-power serial interface 42 used for connecting the microcontroller 32 to the external connector 21 for communication with an external computer or printer (not shown). The connector 21 preferably is a standard telephone jack for connection to black, red, yellow and green (B, R, Y and G) lines as shown.

40 For transmitting data from the microcomputer, serial data from the universal receiver-transmitter 41 (see FIG. 4) are received on a line 120 and fed through a driver including a transistor 121, a series resistor 122, a shunt resistor 123, a load resistor 124 and a feedback capacitor 125 which prevents the interface from generating radio frequency interference. The resistors 122, 123, and 124, for example, have values of 8.2 K ohms, 100 K ohms and 100 K ohms, respectively. The capacitor 125 has a value, for example, of 100 picofarads. The collector of the transistor 121 is connected to the green line G through a first Schottky diode 126. The green line G is also connected to a shunt network including a capacitor 127, to resistors 128 and 129, and a second Schottky diode 130.

45 The first Schottky diode 126 isolates the driver transistor 121 from the impedance network in the absence of the connector 21 being connected to an external computer. Therefore, unless the interface is actually being used to transmit data, it consumes very little power. The capacitor 127 has a value, for example, of 0.1 microfarads, and the resistors 128 and 129 each have a value of, for example, 3.0 K ohms.

50 To receive data, there is provided a level-shifting transistor 131 that is connected to the black line through a series resistor 132. The resistor 132 has a value, for example, of 33 K ohms. A Schottky diode 133 shunts the base and the emitter of the transistor 131 so as to present a more linear impedance to the black line. The transistor 131 operates in connection with a load resistor 134, for example 4.3 K ohms, and a capacitor 135, such as 100 picofarads, that limit the frequency response of the transistor 131 so as to reject high frequency noise or interference.

55 Turning now to FIG. 9 there is shown a hierarchical diagram of various software modules which are

included in the electrically programmable read only memory (31 in FIG. 4) and which define various control procedures that are executed by the microcontroller (32 in FIG. 4) for controlling the photoanalytical device (10 in FIG. 1). At any given time, the microcontroller is either executing an interrupt routine at one millisecond intervals in response to the timer 0 (39 in FIG. 4), or is executing a main program beginning at a certain reset address whenever the reset signal is applied to the microcontroller (see FIG. 4). The software modules therefore include a top-level module 140 called "MAIN" executed in response to the reset signal, and an interrupt routine 141 responsive to the timer 0 interrupt. The interrupt routine includes a module 142 for updating memory locations including a millisecond count and a second count as was described above in connection with FIG. 4.

The main program module 140 is supported by a number of other modules including operating sequences 143 that are further described below in connection with FIG. 10.

A module 144 is used for sending data to a printer or exchanging data with an external computer via the external connector 21 (see FIG. 1). When the photoanalytical device is connected to an external computer, the external computer may program and test the photoanalytical device and obtain results having been accumulated in the random access memory in the device. In particular a manufacturing test module 145 controls the instrument during programming and testing by the manufacturer prior to shipment of the instrument to the customer.

A user interface module 146 includes control procedures for communicating with the operator of the photoanalytical device. The software modules, for example, include a module 147 for scanning the keyboard (15 in FIG. 1), a module 148 for operating the display (17 in FIG. 1), and a module 149 for activating the buzzer or alarm (16 in FIG. 1).

The software modules also include a set of utilities 150 such as subroutines for performing addition, subtraction, multiplication, division, and other numerical operations.

Turning now to FIG. 10 there is shown a hierarchical diagram of software modules which define the operating sequences. The operating sequences are initiated in response to the operator's selection of a control key on the keyboard. (15 in FIG. 1). A program module 151 defines the procedure for setting the program number or activity level in response to the program button (19 in FIG. 3). A reading module 152 defines the countdown procedure that is initiated by the start button (20 in FIG. 3). A control reading module 153 defines the procedure for testing the instrument using a standardized control solution, as initiated by the control button (23 in FIG. 3). A recall module 154 defines the procedure for inspecting results accumulated in the random access memory in response to the recall button 28. Moreover, a clock module 155 is provided for setting the real time clock in response to the clock button (27 in FIG. 3).

It may also be desirable to permit the operator to change the control limits for the photoanalytical device (10 in FIG. 1). For this purpose there is provided a control limits module 156. The procedure defined by the control limits module is initiated by simultaneously pressing the control button (23 in FIG. 3) and the program button (19 in FIG. 3).

Further details of the software modules are disclosed in the code listing of APPENDIX I.

Turning now to FIGS. 11A and 11B there is shown a flowchart which summarizes the control procedures in the software modules of APPENDIX I, beginning with the main program. Since the on/off switch also functions as a reset switch, a flag SW is used to indicate whether the instrument is to be turned on or off in response to the reset signal. The flag is tested in the first step 161. If the flag is a logical zero, then in step 162 the flag is set to a logical 1 and the photoanalytical device is shut off. Therefore, the next time that the on/off switch is pressed, step 161 will find that the flag SW is set to a logical 1 and the instrument will become turned on. Then in step 163 the logical flag SW is set to a logical zero so that if the operator again presses the on/off switch the instrument will turn off.

To turn the instrument on, the ports, timers and flags associated with the microcontroller are initialized in step 164. Next, in step 165, a check sum of the random access memory (30 in FIG. 4) is computed and compared to determine whether any of the control information in the memory is erroneous. Execution branches in step 166 depending upon whether a check sum error was detected.

In the event of a check sum error, it is necessary for the random access memory to be loaded with the control constants that are used, for example, in Equations 2 and 3 above. These constants are obtained in step 168 by entering the manufacturing test mode as defined by the manufacturing test module.

The manufacturing test mode is entered by attaching an external computer to the instrument via the external connector (21 in FIG. 1). The external computer accesses the instrument by first entering a "personal computer mode" in which the instrument recognizes certain control codes. The control code "A" uploads all control test results having been accumulated in the random access memory and transmits these results to the external computer. The control code "C" uploads only the test results made in the current month, and the control mode "L" uploads only the test results for the previous month. The control code "R"

sets the control limits and the code "r" reads or uploads the control limits. The control code "S" sets a system number which identifies the particular instrument, and the code "s" reads or uploads the system number. The control code "T" sets date and time in the real time clock, and the code "t" reads or uploads the date and time. The control code "M" enters the manufacturing test mode. The code "Q" exits the personal computer mode.

In the manufacturing test mode the external computer can download constants into the random access memory. The external computer transmits the constants and a password after the control code "C". The external computer can also operate the instrument to obtain test readings and test the battery condition, the display, keyboard, memory, the crystal frequency, and the buzzer.

In response to the control code "A", the analog circuits are powered up by activation of the "POWER UP" signal in FIG. 4. The battery condition is read or uploaded in response to a control code "B". All of the elements of the display are turned on and off in response to the control code "D".

A keyboard test is initiated in response to the control code "K". In the keyboard test, the buttons on the keyboard must be pressed sequentially and in response the respective digits 1 to 8 are uploaded as corresponding switches are closed.

A memory test is performed in response to the control code "M". The reflectometer in the instrument is tested by first transmitting a control code "R" to perform a dark and reference test, and then transmitting a control code "U" to perform a sample reading.

The real time clock is set by transmitting a control code "S", and the time may be read back by transmitting control code "T". In response to a control code "W", a square wave of approximately 1.371 kilohertz is transmitted on the column B output pin of the microcontroller to provide a test of the crystal frequency. In response to the control code "Z", the buzzer is activated for test purposes. The manufacturing test mode is terminated by the control code "Q".

Returning now to the flowchart in FIG. 11A, once the manufacturing test mode has downloaded the constants, the random access memory should include proper control information including a proper check sum. Therefore, when execution branches back to steps 165 and 166, there should not be a check sum error. Execution then branches to step 169 to test whether the system identification number and the program number are both not equal to zero.

The system id and the program number are both set to zero during the manufacturing test mode when the constants are loaded. Therefore, initially execution will branch to a step 170 in which the display is first tested by displaying all digits and legends. Then in step 171 the operator must press the "change" button to set the system identification number and program number to non-zero values. The user exits the "change" mode by pushing the on/off button which causes execution to jump back to the initial step 161 and execution should continue back down to step 169 whereupon the microcontroller should find that the system id and the program number now have non-zero values. Therefore execution branches via the on-page connector A to step 172.

In step 172 the microcontroller checks whether the operator is requesting a "change limits" mode by pressing simultaneously the control and program buttons when the on/off button is pressed and released to turn the unit on. The system number, units and control limits are successively displayed in step 173. This control information can be changed by pressing the "change" button and then pressing the forward or reverse buttons to increment or decrement the displayed value. The control limits mode is terminated by pressing the on/off button.

In step 174 the microcontroller checks whether the "start" button was pressed when the on/off button was pressed and released. If so, the microcontroller executes a "self test" mode. In step 175 the microcontroller checks for a low battery condition, checks the dark current value, checks the reference current value, and also turns all of the display elements on and off. The self test mode is terminated by pressing the on/off button.

In step 176 execution reaches a point of typical operation by displaying a previously entered program number and waiting for the operator to press either the program, start, control, recall or clock buttons. The instrument would also respond to any commands from an external computer connected via the external connector by entering the personal computer mode. Also, as further described below, the microcontroller could be programmed to function as an alarm clock to remind the operator that a calibration or test reading should be taken.

If the program button is pressed, as detected in step 177, then the operator may change the program number in step 178.

In step 179 the microcontroller checks whether the start button is pressed. If so, then in step 180 the 60-second count down sequence is initiated. The dark, reference and sample values are read, and the concentration is computed. If the instrument is issued to a patient, the date, time, system number and

concentration are recorded in the random access memory for review by a physician at a later time.

Continuing now in FIG. 11B, in step 181 the microcontroller checks whether the control button was pressed. If so, then in step 182 the message "CCC" is displayed if the random access memory is full. In this case the results having been recorded in the memory must be dumped or uploaded before the control sequence can proceed further. Otherwise there is sufficient memory to continue the control sequence. The operator number and control type are displayed and the operator may change them. Otherwise, the operator may press the "start" button to initiate a 60-second count down. The dark and reference currents are read and the reflectance of the sample is read. The concentration is computed and the date, time, operator number and concentration are recorded in the random access memory.

In step 183 the microcontroller checks whether the recall button was pressed. If so, then in step 184 data is recalled from the random access memory and displayed. The system number, new month and stored readings are displayed. Also, if a calibration or treatment schedule is stored in the random access memory, readings that are missing or not taken at appropriate times are indicated, for example, by activating the buzzer and flashing the display of the inappropriate or late results.

In step 185 the microcontroller checks whether the "clock" button is pressed. If so, then in step 185 the year, month, day, hour and minute are displayed in sequence as the clock button is pressed multiple times. A displayed value can be changed by pressing the change button and then the forward or reverse buttons to increase or decrease the displayed value.

In step 187 the microcontroller checks whether a byte of information has been received in the input buffer of the universal receiver-transmitter (41 in FIG. 4). If so, then in step 188 the microcontroller checks whether the byte is a control code for the personal computer mode, and any indicated command is executed, as described above.

The random access memory could store a calibration or treatment schedule, for example, in the form of a table of the times of the day in which a calibration or test reading should be taken. If there is such a schedule, then in step 189 the microcomputer obtains the next scheduled treatment time from the table and also obtains the current time from the real time clock. Then in step 190 the buzzer is activated periodically if the current time exceeds the scheduled time. To conserve the batteries, for example, a short buzz or series of buzzes is emitted at 15 minute intervals until the scheduled calibration or test is performed.

Turning now to FIG. 12 there are shown more detailed flowchart steps for operating the buzzer or alarm to tell the operator that a scheduled calibration or treatment has been missed. In step 191 the time of day from the real time clock is compared to the next scheduled time for calibration or treatment. If the time of day exceeds the scheduled time, then in step 192 the difference between the minutes of the time of day and the scheduled time is compared to 1, 15, 30 and 45. If the difference in the minutes is equal to 1, 15, 30 or 45 then in step 193 the alarm is turned on. In step 194 the microcontroller waits for half a second and then in step 195 the alarm is turned off.

Turning to FIG. 13 there are shown flowchart steps for obtaining the next scheduled calibration or treatment time. A new value for the scheduled time is obtained after a step 200 in which a reading is taken and the reading is recorded in the random access memory. Then, in step 201 the microcontroller looks in the schedule table for the next time of day after the current time of day indicated by the real time clock (33 in FIG. 4). In step 202 the scheduled time (TSCED) is set equal to that next time of day from the schedule table.

The microcontroller can also be programmed to recall results that have been stored in the random access memory and to indicate whether a calibration or treatment schedule has been followed. This feature could be used, for example, to indicate to a parent or guardian that an appropriate test was not taken at an appropriate time. In the recall mode, after the operator presses the recall button, in step 210 the microcontroller obtains the time of a reading having been stored in the random access memory. Then, in step 211, the microcontroller computes the difference between the recalled time and the scheduled time and determines whether that difference is greater than 15 minutes. If so, then in step 212 the display of the recalled time is flashed and the buzzer is activated for half a second.

To obtain the next scheduled time, in step 213 the microcontroller looks in the schedule table for the next time of day after the recalled time. Then, in step 214 the scheduled time (TSCED) is set to the next time of day from the table. These steps are repeated for the other readings recalled from the random access memory.

In view of the above, there has been described a portable photoanalytical device that is readily programmed for particular reagent test strips, operators and users, and in which the calibration and performance of the device is documented. Constants for translating reflectance readings into concentration values and control limits for detecting erroneous operation of the device are downloaded from an external computer to a battery-backed RAM chip within the device.

By computing and storing a check sum in the memory, the integrity of the control information is assured. The integrity of the data stored in the RAM is also protected during the insertion and removal of a set of main batteries, and during low-battery conditions prior to battery replacement.

The check sum can indicate whether the device has been initially programmed with control constants and limits. The random access memory can also retain the previously used program number or activity level. This helps to eliminate operator error in entering a proper program number.

To monitor the calibration and performance of the device, there is provided a battery-backed real time clock so that the current date and time can be recorded automatically in the memory when readings are taken. The real time clock could also be used for reminding an operator that a calibration or test reading should be taken according to a schedule stored in the random access memory and also readings that are not taken at the scheduled times can be indicated.

Claims

- 15 1. A portable photoanalytical device for reading reagent test strips, said device comprising:
a random access memory (RAM) chip within said photoanalytical device,
battery means for maintaining information within said RAM chip;
external connector means for downloading information into said random access memory (RAM) chip, said
20 downloaded information providing said device with at least one constant value capable of being used by the
device in a software program for translating reflectance readings into concentration values;
switching means for initiating execution of said software program for taking a reflectance reading from a
reagent test strip within said device and comparing said reflectance reading to an internal standard and
translating the reading to a concentration value using said constant value and storing said concentration
25 value within said RAM chip, the stored concentration value capable of being outputted through said external
connector means; and
internal data integrity (IDI) means for determining whether said information maintained within said RAM chip
is erroneous and displaying an appropriate message in the event that said information is erroneous.
2. The device of claim 1 including a microprocessor for executing said software program.
- 30 3. The device as claimed in claim 2 further comprising a battery-backed real time clock, and wherein
said microprocessor is programmed for providing an alarm clock means for alerting an operator to take
readings at certain times.
4. The device of claim 2, further comprising low-power serial interface means for connecting said
external connector means to said microprocessor.
- 35 5. The device of claim 1 wherein said IDI means includes means for summing said information
maintained within the RAM chip and comparing the sum to a previously computed sum having been stored
in the RAM chip.
6. The device of claim 5 wherein said means for summing and comparing is operative each time the
device is turned on.
- 40 7. The device of claim 5 wherein the IDI means provides a low battery indication.
8. A method of reading a reagent test strip, said method comprising the steps of:
downloading control information into a portable hand-held photoanalytical device by means of an external
connector means whereby said control information is retained within a random access memory (RAM) chip
within said photoanalytical device, said control information being maintained within said RAM chip by
45 means of a battery means;
inserting a reagent test strip into said photoanalytical device;
activating a switching means and thereby initiating execution of a software program to use said control
information for taking a reflectance reading from the reagent test strip, comparing said reading to an internal
standard and converting said reading into a concentration value, said value being stored within said RAM
chip, said stored value capable of being outputted through said external connector means; and
50 monitoring internal data integrity ("IDI") using an IDI means, said IDI means being capable of determining
whether said information maintained within said RAM chip is erroneous and displaying an appropriate
message in the event that said information is erroneous.
9. The method of claim 8 further including reading a battery-backed real-time clock and operating an
alarm to prompt an operator to take readings at predetermined times.
- 55 10. A method of operating a portable photoanalytical device for reading a reagent test strip, said
photoanalytical device including a random access memory (RAM) within said photoanalytical device, a
battery for powering said RAM to maintain information within said RAM, a keyboard for obtaining an activity

value for said reagent test strip from an operator, a display for displaying information to said operator, a
microprocessor executing a software program including a procedure for taking a reflectance reading from
said reagent test strip, comparing said reflectance reading to an internal standard and translating the
reading to a concentration value by said procedure using constant values maintained in said RAM and using
5 said activity value, and an external connector through which said constant values are downloaded to said
RAM, said method comprising the steps of:
a) executing software instructions with said microprocessor to determine whether said RAM has
stored within it said constant values which are not erroneous, and if not, requiring constant values to be
downloaded through said external connector,
10 b) executing software instructions with said microprocessor to display to said user an activity value
having been stored in said RAM and permitting said operator to use said keyboard to change said activity
value,
c) executing said procedure of said software program to take a reflectance reading from said reagent
test strip, compare said reflectance reading to said internal standard and translate the reading to a
concentration value by using said constant values maintained in said RAM and said activity value.
15

20

25

30

35

40

45

50

55

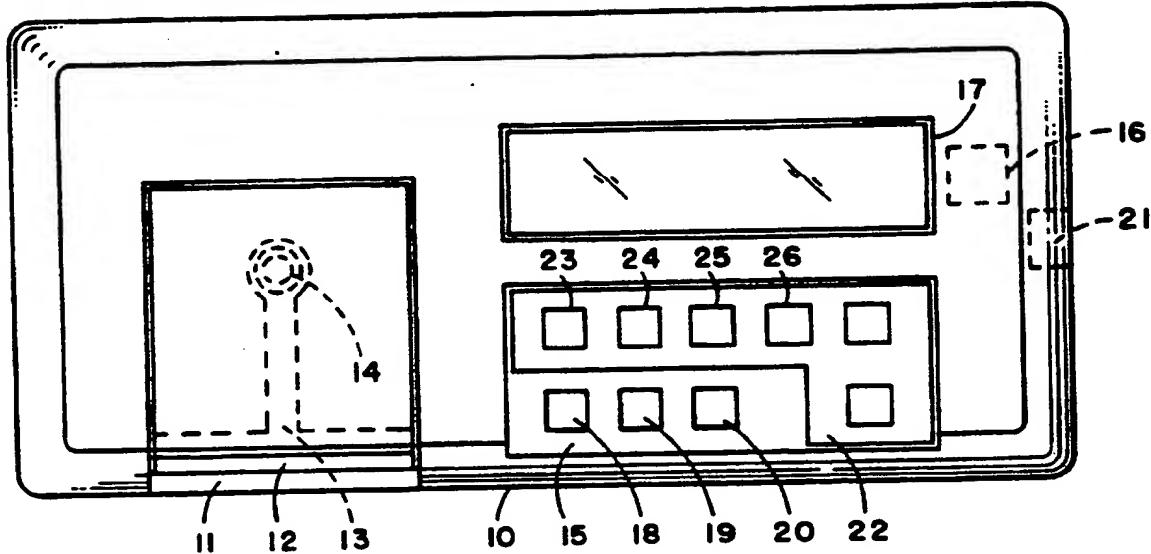


FIG. 1

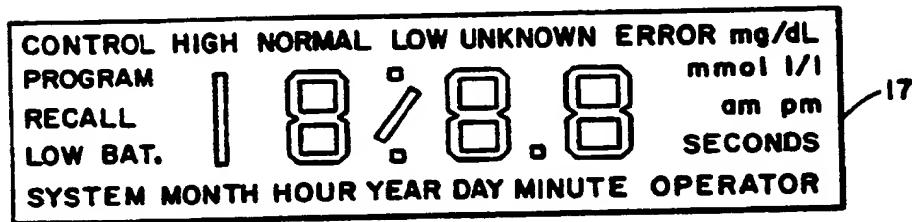


FIG. 2

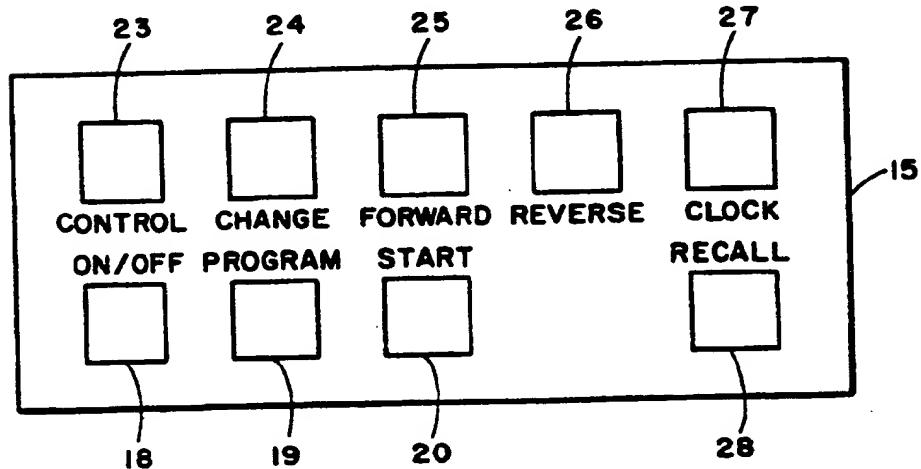


FIG. 3

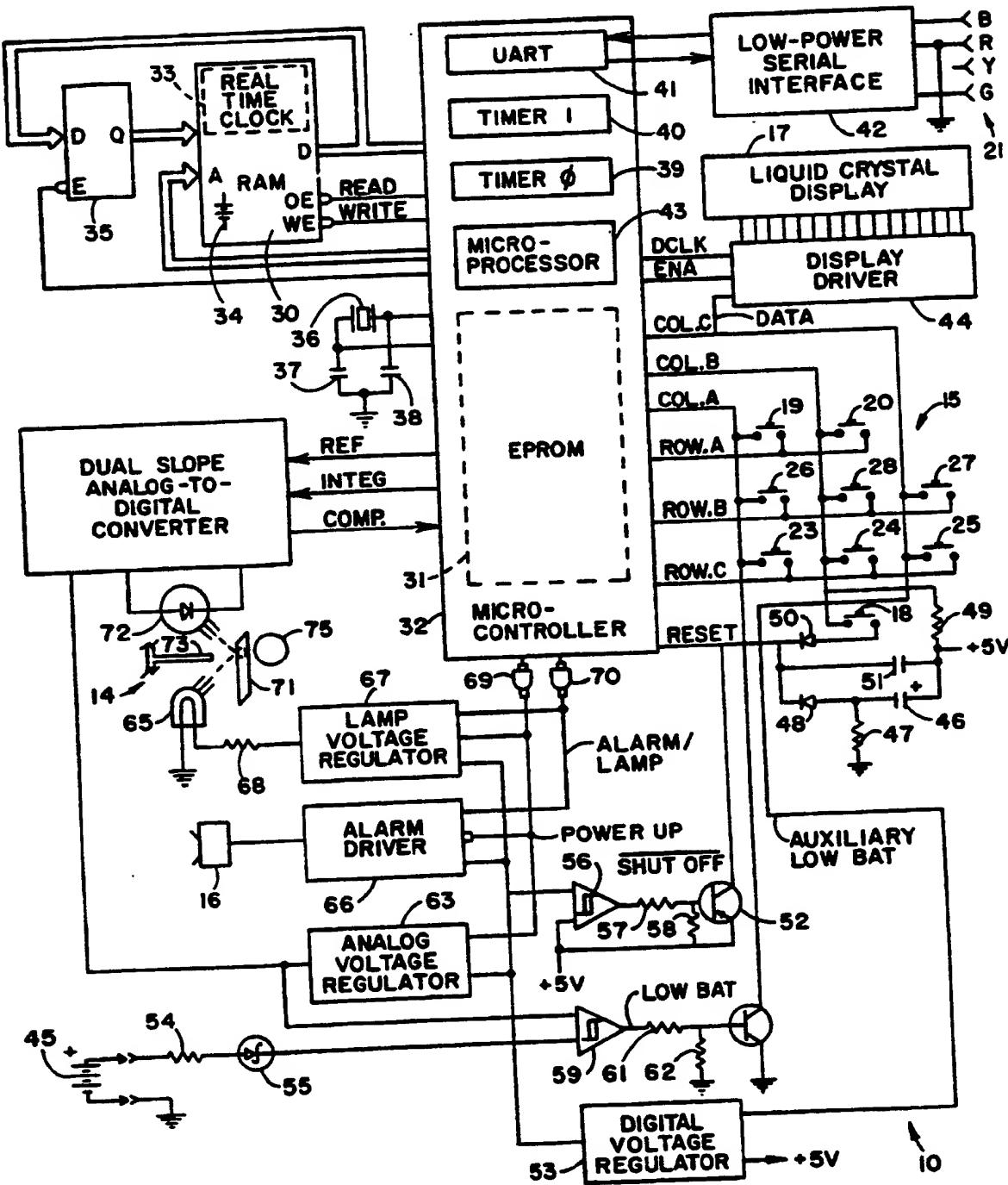
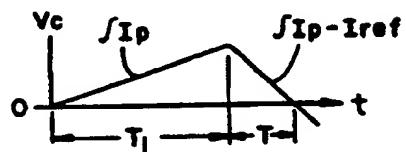
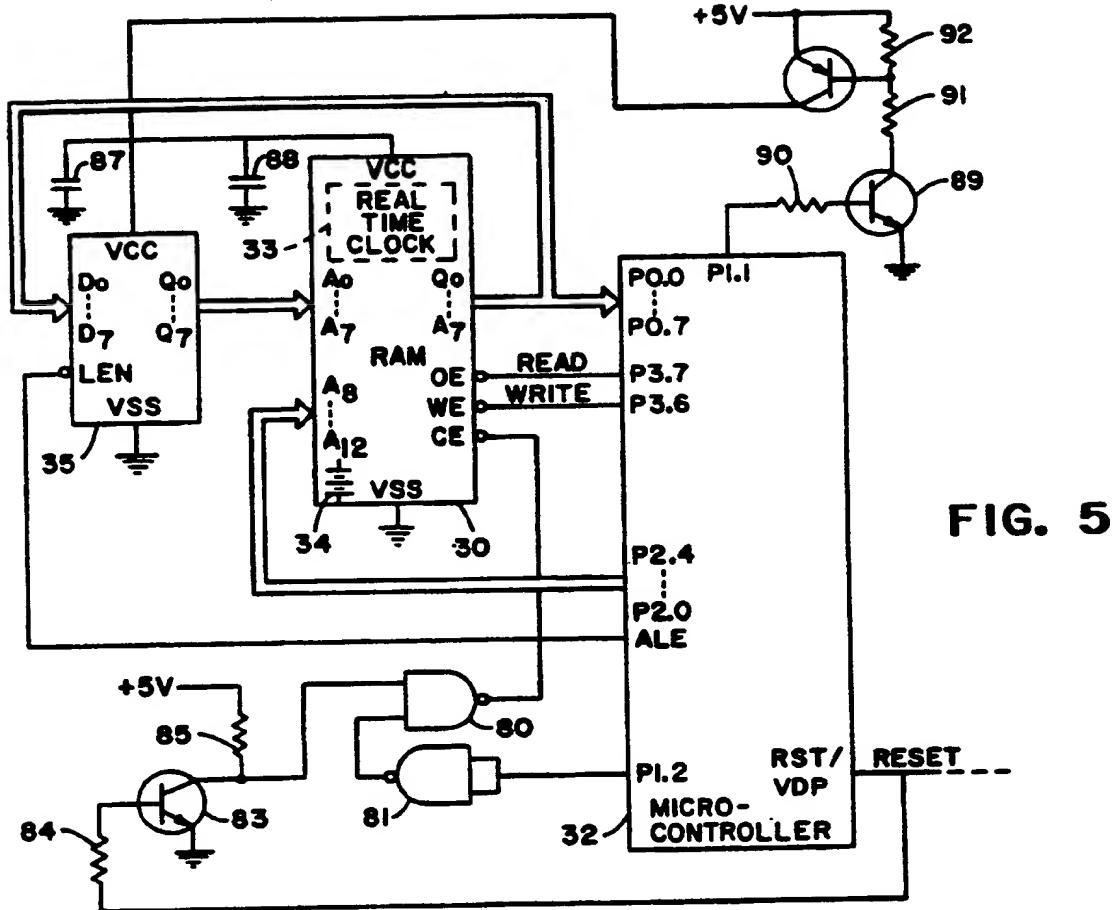
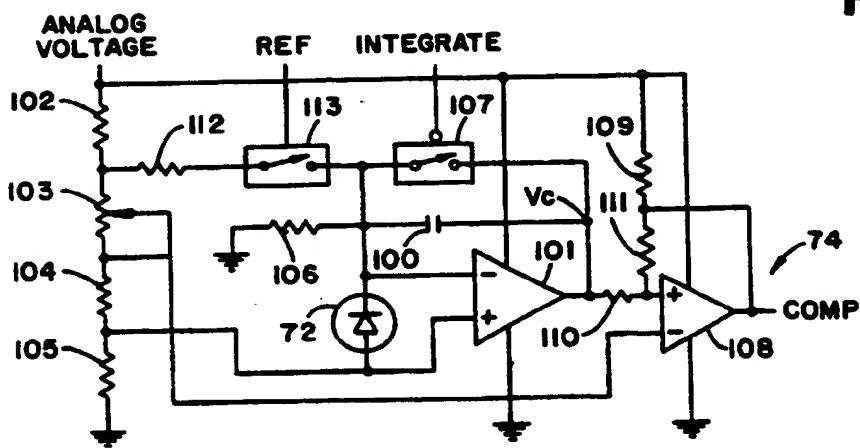


FIG. 4

**FIG. 6**

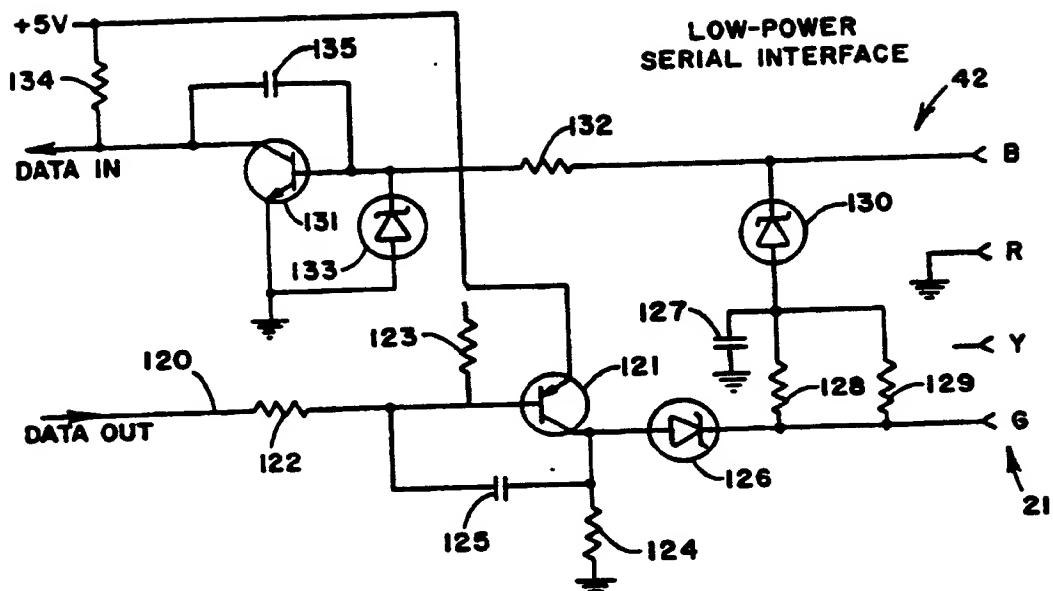


FIG. 8

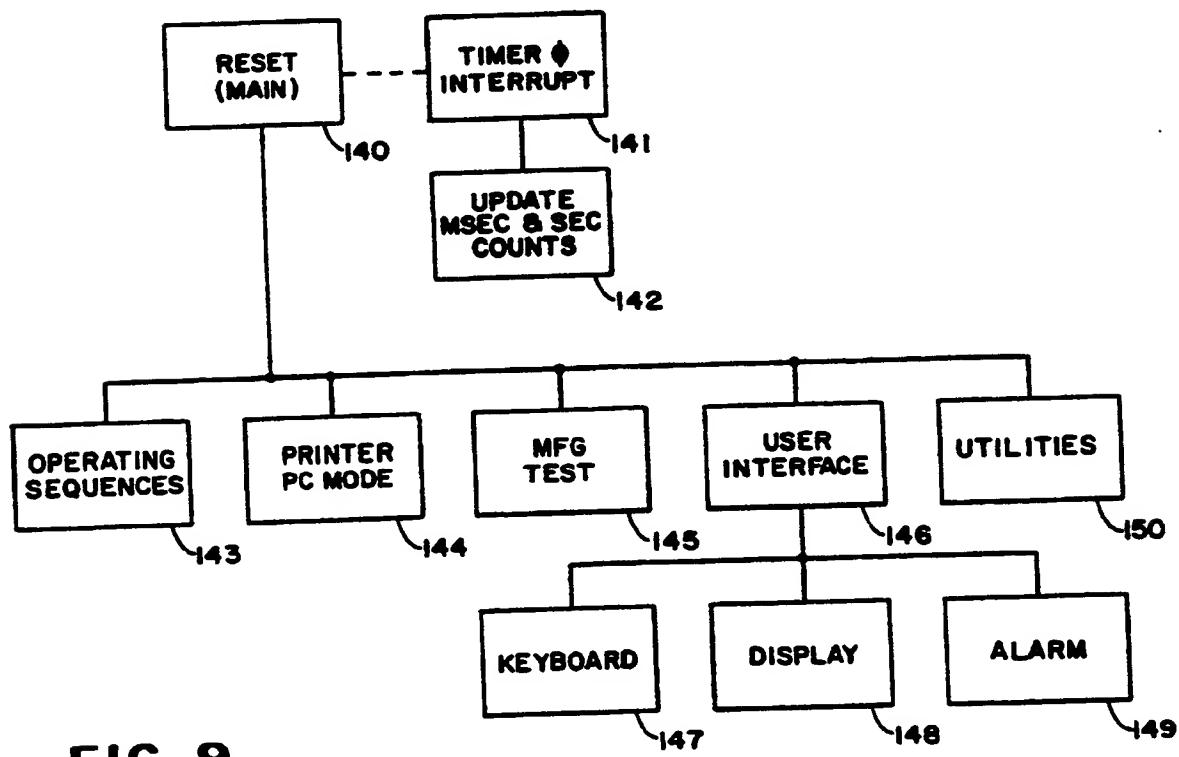


FIG. 9

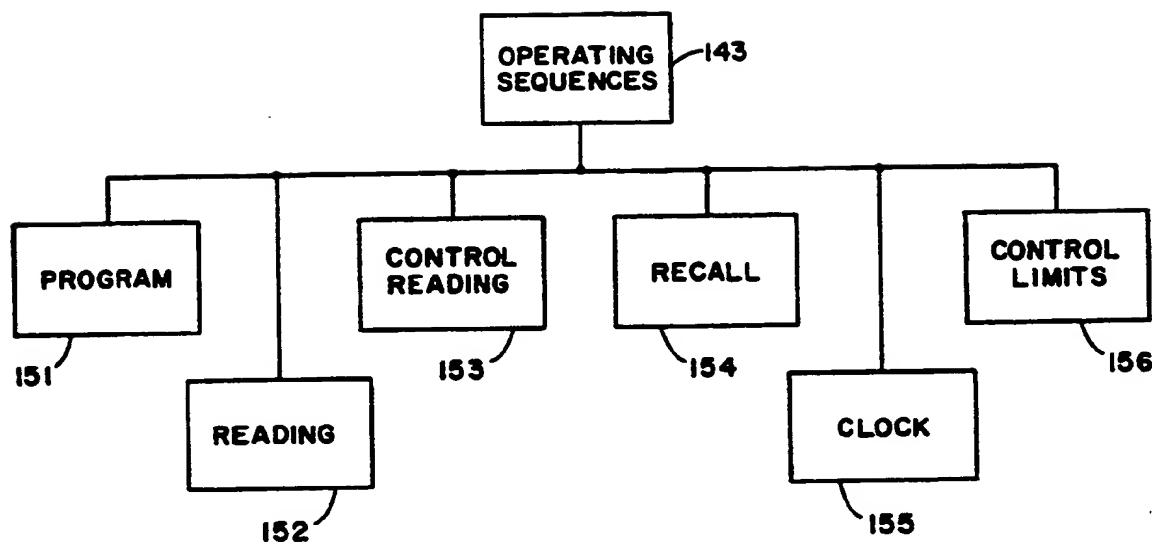


FIG. 10

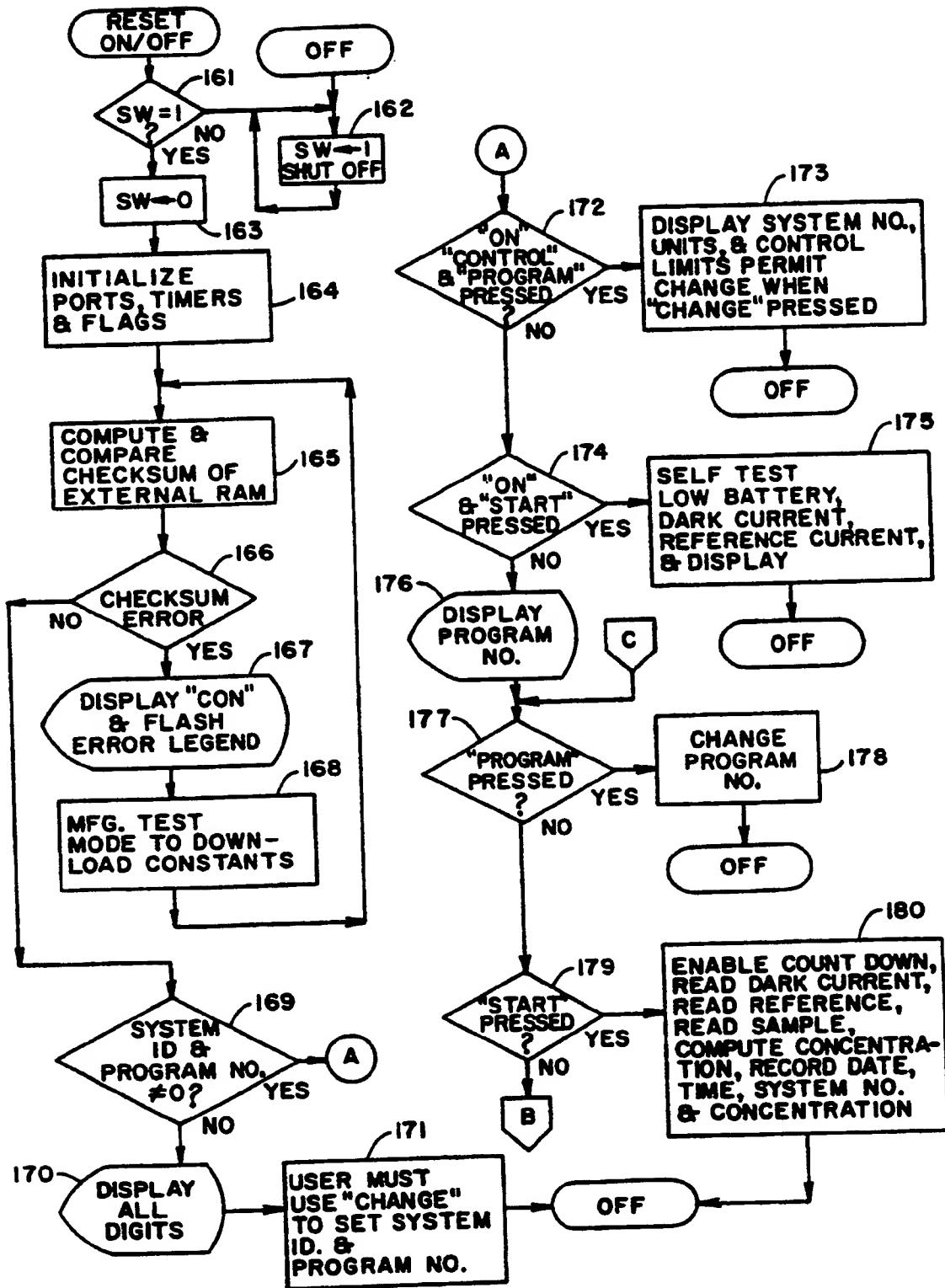


FIG. IIa

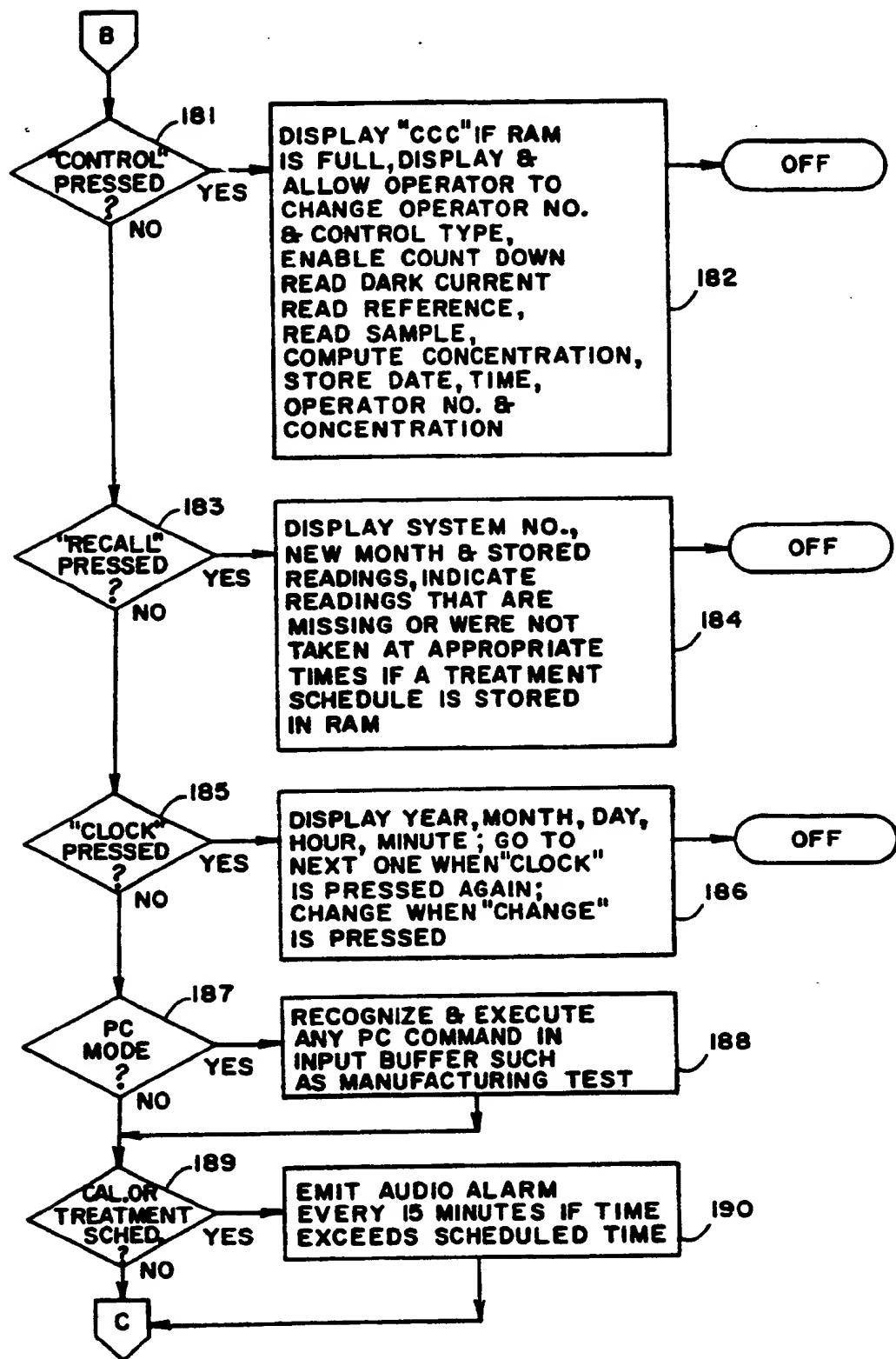


FIG. IIb

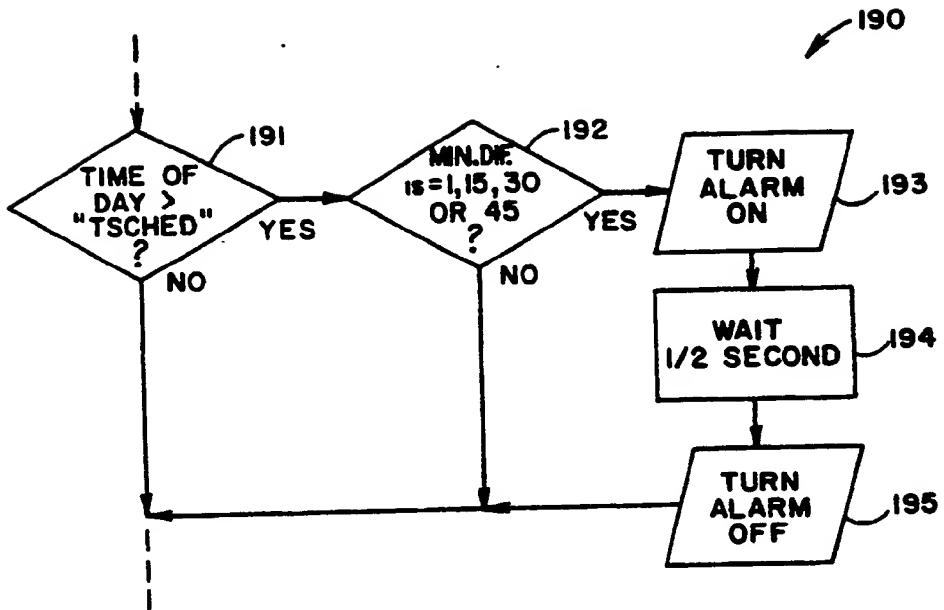


FIG. 12

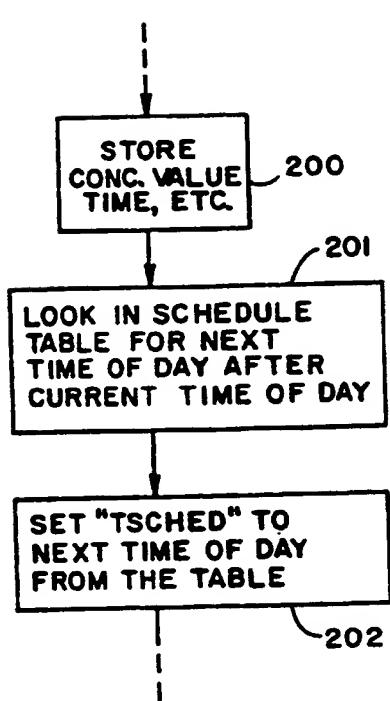


FIG. 13

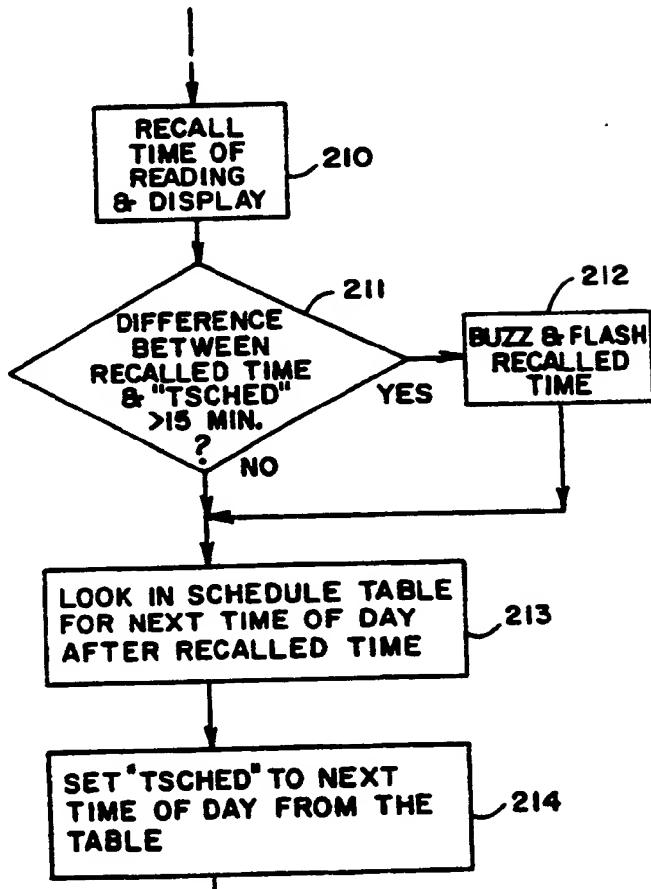


FIG. 14

APPENDIX I
Copyright (C) 1989 Miles Inc.

5

SOFTWARE MODULES

```
main()
{
    initialize ports, timers, flags
10
    if CONTROL and PROGRAM are pressed
        ctrl_limits()

    else if START is pressed
15
        self test

    else if FORWARD, REVERSE, and PROGRAM are pressed
        start_up()

20
    program()

    repeat forever

        if PROGRAM was pressed
25
            program()

        else if START was pressed
            read()

30
        else if CONTROL was pressed
            ctrl_read()

        else if RECALL was pressed
            recall()
```

MS 1566-EP

```
        else if CLOCK was pressed
            clock()
        }

5      }

program()
{
    display program number
10
    if the meter was just turned on and an out of
    range
        control has been run in the current or
    previous
15
    month and has not been rerun within range by
    the same operator flash "error"

    while key pressed not in (CONTROL, CLOCK, RECALL,
    START)
20
    if key pressed was PROGRAM
        increment program number
        if program number > 8
            program = 1
25
    }
}

rdct_inc

30
    handle interrupt for timer 1
    increment read counter
}

adc

MS 1566-EP
```

```
turn on analog voltage
if this is not a dark read
    wait 16 msec
5      turn on bulb
wait 1 sec
turn on INT
wait for COMP to go high, 7 sec timeout
wait 666 msec
10     turn on REF
start counting
wait for COMP to go low, 230400 count max
stop counting
test dark limits
15     store T + T1
}

read_sample

20     read sample
store Is
R = Rfs * (Is-Ios)/(Ifs-Ios)
if in self test mode
    alternate display until ON/OFF is pressed
25     else
calculate concentration (Equation 3)
}

read_dark_ref

30     read dark
store Ios
read reference
store Ifs - Ios
```

MS 1566-EP

```
if in self test mode
    read sample
}

5      read

        read dark and reference
        if countdown is enabled
            count down
10     read sample
}

control

15     fill display for 1 sec, retain while CONTROL is
        pressed

        if the meter is full
            display "CCC"
20     else
            display and allow to change operator number,
            control type

        if this is a system control
25     set the program number to 5

        count down
        store reading
        display reading
30     flash "error" if reading is out of range
}

store
```

MS 1566-EP

```
    read clock chip
    if the month has changed
        new_month
    store reading
5     update control error record
    update reading and header data structures
}
recall
10
    display the system number for 1 sec
    read clock chip
    if the month has changed
        new_month
15     display the number of free readings
    while key pressed no in (CLOCK, CONTROL, PROGRAM,
        START)
        if attempting to go past )
            buzz
20     else
            if key pressed was REVERSE
                decrement field
                if done with this reading
                    look at previous reading
            else
                increment field
                if done with this reading
                    look at next reading
25
30     case (field)
0:     display " - "
1:     display concentration
2:     display operator number
3:     display time of reading
```

MS 1566-EP

```
        4:    display date of reading
    }
    wait (to handle acceleration)
}
5 }

clock

read clock chip
10   display year

if CHANGE is pressed
    change year

15   if CLOCK is pressed
    display month, date

if CHANGE is pressed
    change month

20   if CHANGE is pressed
    change date

if CLOCK is pressed
25   display hour, minute

if CHANGE is pressed
    change hour

30   if CHANGE is pressed
    change min
}

ctrl_limits
```

MS 1566-EP

```
display system number

wait until CHANGE or CONTROL is pressed
5      if CHANGE was pressed
            change system number

display units
wait until CHANGE or CONTROL is pressed
10     if CHANGE was pressed
            change units number

repeat forever
    display the next control limit
15    wait until CHANGE or CONTROL is pressed
        if CHANGE was pressed
            change the control limit
        }
    }

20 print_pc

wait unit a 'C', 'L', or 'P' is received by the
serial port
25     if the character was a 'C' or 'L'
            printer dump

else repeat until a 'Q' is received
    case (char received)
30        'A'
        'C'
        'L':     printer dump
        'M':     manufacturing test
        'R':     set control limits
```

MS 1566-EP

```

      'r':      output control limits
      'S':      set system number
      's':      output system number
      'T':      set time
      5        't':      output time
      'U':      set units
      'u':      output units
      }
      }
      10       reset
      }

      print_dump

      15       read clock chip
      if month has changed
      new_month

      if there are any readings to s}

      20       for each reading to be output
      if this is the first reading for a new
      header
      put header
      25       if this is the first reading in its block
      put DLE, STX, block number

      put reading

      30       if this is the 500th reading to a printer
      end block
      flash unit transfer is re-initiated
      by the printer
      re-put the previous header

```

MS 1566-EP

```
        if this is the last reading
            end block

5          if 17 readings have been sent in this
                  block or there is a new header for the
                  next reading
                  end block
              }

10         else
                  send a header and a empty reading block
                  reset
              }

15         putc

                  put a char
                  if the char is a DLE
                      put it again
20                  update checksum
              }

blk_end

25         put DLE, EOT or ETX, checksum
                  if the received character is an ACK
                      set pointers for next block
                  else
                      reset pointers to last block
              }

30         put_header

                  put DLE, SOH, block number, header data
```

MS 1566-EP

```
    put present date
    end block
}

5      put_reading

        put reading data
    }

10     mfg

        repeat until a 'Q' is received
        case (char received)
            'A':      turn on analog voltage
15      'B':      repeat low battery test until
                    next character
            'D':      alternate display
            'I':      initialize meter
            'K':      keyboard test
20      'M':      memory test
            'P':      dark and reference test
            'R':      read test
            'U':      %R test
            'S':      set time
            'T':      output time
            'W':      crystal test
            'x':      case (char received)
                    'c': calculate new checksum
                    'g': get data into external memory
30      'p': put data from external memory
                    'x': put header and reading pointers
                }
            'z':      buzzer test
        }
```

MS 1566-EP

```
        }

    }

scan
5
    enable reset
    set key matrix column A low, B & C high
    scan key matrix inputs

10     set column B low, A & C high
    scan key matrix inputs

        set column C low, A & B high
        scan key matrix inputs

15     disable reset
}

key_released
20
    wait until no key is pressed for at least 20 msec
}

disout
25
    clock out 48 bits from disbuf to the display
    driver
}

30     cirdsp

        clear display (except for "lowbat")
}
```

MS 1566-EP

```
err

    display "Err"
    reset
5     }

bars

    display "----"
10    }

dis

    if the number <2000
    display it
15    else
        display 'Err'
    }

20    dis_reading

        display the units
        if the concentration is low
            display "LO"
        else if it is high
            display "HI"
        else
            display the concentration
    }

25    dis_ctrl_mode

        display the control type
    }

MS 1566-EP
```

```
flash_err

    flash "error" until the desired key is pressed
5      }

ticktimer

    set up timer 0 as an 8 bit auto-reload timer,
10      interrupting every 1 msec
    set up timer 1 as a baud rate generator for 9600
baud
}

15    millisec

    handle timer 0 interrupt
    update msec and sec counts
    time out after 180 sec with no key pressed
20      }

wait

    wait for a given number of msec
25      }

getchar

    wait for a character to be received by the UART
30      return the character
}

outchar
```

MS 1566-EP

```
transmit a character out the UART
}

get
5    receive an integer in ASCII
      return the integer
}
10   put
      transmit an integer in ASCII
}
15   putin
      transmit an integer in ASCII
      transmit a (CR) (LF)
20   }
prv
      return an index to the previous reading
25   }

nxt
      return an index to the next reading
30   }

loadptr
      load the external memory data pointer
```

MS 1566-EP

```
    }

bulbtest

5      turn on analog voltage
      wait 16 msec
      turn on bulb
      wait 2 sec
      set low battery flag
10     }

new_checksum

15     calculate a new checksum for the portion of
       external memory
       containing reading data
       if just turned on
       perform a low battery test
}
20     new_header

       if no control readings have been taken since the
       last header
25     rewrite current header
       else
       create new header
}

30     new_month

       delete previous month's headers
       update pointers so that the current month becomes
       the previous

MS 1566-EP
```

```
        month
        create a new header
        update control error record
    }

5      time

        send access code to clock chip
        if reading time
10     read time from clock chip
        else
        write time to clock chip
    }

15     recog
        send access code to clock chip
    }

change

20     repeat until a terminating key is pressed
        if b
            display
        else
            clear
25     wait until FORWARD, REVERSE or terminating key
pressed,
        300 msec max
        repeat while FORWARD or REVERSE is pressed
            increment or decrement parameter
            display parameter
            if changing time
                update clock chip
            if changing units or a control limit
```

MS 1566-EP

```
        if changing units
            convert control limits
            make new header
            wait (to handle acceleration)
5          b = not b
        }
    }

change_dis
10
    if changing the hour
        set am or pm
    if changing the month or hour
        if changing the hour and the hour ) 12
15        display hour-12, minute
    else if changing the hour and the hour is 0
        display 12, minute
    else
        if changing the units
20        display units
    else
        if changing a control limit and
units = mmol
            set decimal point
25        display other, n
    }

initialized

30
    return true if the initialized code is written in
    external
        memory
    }
```

MS 1566-EP

start_up

fill display
initialize variables
5 wait for CHANGE to be pressed
change system number
wait for PROGRAM to be pressed twice
write initialized code to external memory

10 Constants

Rfs	0.907
G0	0
G1	1.0
A	278.5
B	-695
C	465
D0	37701
D1	-68202
E0	.35
E1	0.01

MS 1566-EP



Europäisches Patentamt
European Patent Office
Office européen des brevets



(11) Publication number:

0 387 630 A3

(12)

EUROPEAN PATENT APPLICATION

(21) Application number: 90104075.8

(61) Int. Cl. 5: G01N 21/78

(22) Date of filing: 02.03.90

(30) Priority: 13.03.89 US 324403

(71) Applicant: MILES INC.
1127 Myrtle Street
Elkhart, IN 46515(US)

(43) Date of publication of application:
19.09.90 Bulletin 90/38

(72) Inventor: Hurtle, Richard L.
23549 U.S. 33 East
Elkhart, Indiana 46515(US)
Inventor: Vavul, Thomas E.
10193 Parkwood Drive, Apt. Nr. 1
Cupertino, California 95014(US)

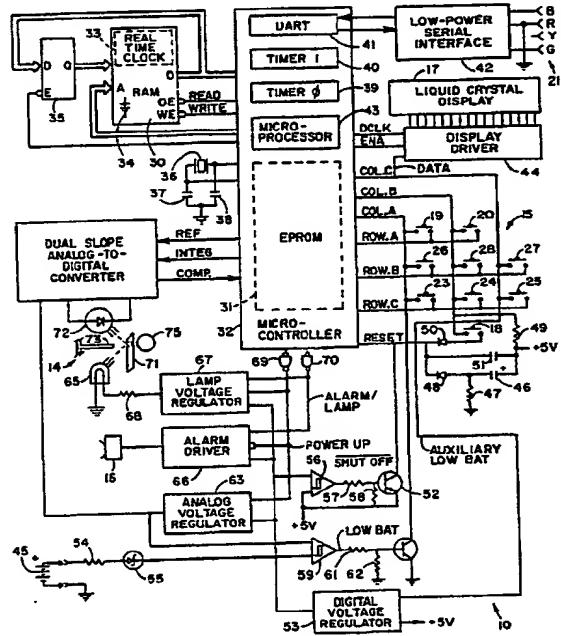
(84) Designated Contracting States:
DE FR GB IT

(74) Representative: Kirchner, Dietrich, Dr. et al
c/o BAYER AG Konzernverwaltung RP
Patentabteilung
W-5090 Leverkusen, Bayerwerk(DE)

(88) Date of deferred publication of the search report:
27.11.91 Bulletin 91/48

(54) A compact semi-programmable device for reading reagent test strips and method relating thereto.

(57) A portable photoanalytical device takes a reflectance reading from a reagent test strip, compares the reading to an internal standard, and translates the reading to a concentration value using constant values stored within a RAM chip. The constant values are preprogrammed for a particular lot of reagent test strips. A battery maintains the information stored in the RAM. The control values are initially downloaded into the RAM via an external connector. The concentration values are accumulated in the RAM, and periodically dumped out of the device through the external connector. The integrity of the information stored in the RAM is monitored by computing a checksum. Preferably the device includes a battery-backed real-time clock providing the date and hour of each reading. The device can also be operated by an external computer for test purposes.





European
Patent Office

**EUROPEAN SEARCH
REPORT**

Application Number

EP 90 10 4075

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.5)		
Y	US-A-4 685 059 (H YAMAMOTO) * column 3, line 3 - column 4, line 62 * - - -	1,2,4-8, 10	G 01 N 21/78		
Y	EP-A-0 221 357 (OXIMETRIX INC.) * page 5, line 40 - line 51 * - - -	1,2,4-8, 10			
A	EP-A-0 182 647 (HOME DIAGNOSTICS INC) * page 10, line 7 - line 19 ** page 18, line 7 - page 19, line 24 ** page 21, line 6 - page 22, line 12 * - - -	1,8,10			
A,D	US-A-4 731 726 (L M ALLEN III) * column 6, line 51 - column 8, line 36 * - - -	1-10			
A	EP-A-0 290 683 (DIVA MEDICAL SYSTEMS B.V.) * page 6, line 49 - page 7, line 7 * - - - -	1-10			
			TECHNICAL FIELDS SEARCHED (Int. Cl.5)		
			G 01 N A 61 B		
The present search report has been drawn up for all claims					
Place of search	Date of completion of search	Examiner			
The Hague	01 October 91	HODSON C.M.T.			
CATEGORY OF CITED DOCUMENTS					
X: particularly relevant if taken alone					
Y: particularly relevant if combined with another document of the same category					
A: technological background					
O: non-written disclosure					
P: intermediate document					
T: theory or principle underlying the invention					
E: earlier patent document, but published on, or after the filing date					
D: document cited in the application					
L: document cited for other reasons					
&: member of the same patent family, corresponding document					